Section 5

JUL 14 2006

510(k) SUMMARY

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements ...." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME:

GYNECARE MORCELLEX* Tissue Morcellator

PREDICATE DEVICE NAME:

GYNECARE X-TRACT* Tissue Morcellator

Device Description

The GYNECARE *Morcellex** Tissue Morcellator is a single-patient-use device. The device is inserted into the patient with the use of the provided single-patient-use Obturator. The device allows tissue to be grasped with a standard grasping instrument extended through its central lumen. The tissue can be drawn up inside the device's central lumen into the inner stationary sheath as the exposed blade cuts the tissue. The physician can activate the GYNECARE *Morcellex* Tissue Morcellator via a foot pedal or via the dual-function Blade Guard/Activation Trigger on the device's Detachable Handle. The device can operate in either coring or peeling mode based on the degree of exposure of the blade and placement of the rotatable Coreguard. The device is packaged with a single-patient-use reducer cap to allow the optional use of a 5mm instrument.

The variable-speed, reversible GYNECARE Motor Drive Unit

	(MDU) drives the rotation of the blade of the GYNECARE *Morcellex* Tissue Morcellator at a controlled speed and torque after connection of the device to the MDU via the Flexible Drive Cable. An operating room staff member outside of the sterile field controls the direction and speed of rotation on the MDU.
Intended Use	The GYNECARE *Morcellex* Tissue Morcellator is intended for gynecologic, urologic and general surgical endoscopic use by trained professionals in hospital environments and ambulatory surgery centers.
Indications Statement	The GYNECARE Morcellex Tissue Morcellator is indicated for cutting, coring and extracting tissue during operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures, and laparoscopic gynecologic procedures.
Technological Characteristics	The modified device has the same technological characteristics as the predicate device. The form, fit, function and method of operation are similar.
Performance Data	The bench testing provided in this 510(k) shows that there is less force required to pull simulated tissue through the Morcellex device than is required for the existing device.
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.
Contact	Bryan Lisa Senior Regulatory Associate ETHICON, INC. Rt. 22 West Somerville, NJ 08876-0151 Phone: (908) 218-3392 Fax: (908) 218-2595

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 14 2006

Mr. Bryan Lisa
Senior Regulatory Affairs Associate
Ethicon, Inc.
Ethicon Women's Health & Urology
P.O. Box 151, Route 22 West
SOMERVILLE NJ 08876

Re: K061050
Trade/Device Name: GYNECARE MORCELLEX* Tissue Morcellator
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: April 14, 2006
Received: April 17, 2006

Dear Mr. Lisa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K061050

Device Name: **GYNECARE MORCELLEX* Tissue Morcellator**

Indications for Use:

The GYNECARE MORCELLEX Tissue Morcellator is indicated for cutting, coring and extracting tissue during operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures, and laparoscopic gynecologic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G) David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061050